REMARKS

Confimation of Information Disclosure Statment correction

The Examiner has noted that one of the patents listed in the Information Disclosure Statement, U.S. Patent No. 6,014,846, has subject matter unrelated to the pending application. The examiner has uncovered another patent, U.S. Patent No. 6,048,846, which he believes to be the correct patent, having the correct name and date of issuance as listed in the Information Disclosure Statement and appropriate subject matter. Applicants acknowledge the typographical error and confirm that U.S. Patent No. 6,048,846 is the correct patent.

Amendments to Claims 20, 25, 26, 28 and 37

Claims 20, 25, 26, 28 and 37 have been amended. No new matter has been added and support for the amendments is provided in the original claims and throughout the specification.

Claims 21 and 22

The Examiner has rejected Claims 21 and 22 under 35 U.S.C. §102(b) as being anticipated by McCarty (U.S. Pat. No. 5,789,401) or McCarty (U.S. Pat. No. 5,929,066). These claims have been cancelled.

Claims 1-37 are not obvious

The Examiner has rejected Claims 1-37 as being unpatentable over McCarty (U.S. Pat. No. 5,789,401) or McCarty (U.S. Pat. No. 5,929,066) in view of De La Harpe (U.S. Pat. No. 5,948,772), Jensen (U.S. Pat. No. 5,194,615) and Brand-Miller (*Am. J. Clin. Nutr.* 59(suppl):747S-752S, 1994). De La Harpe discloses composition with chromium tripicolinate or nicotinate and methods of treatment using these compositions. Jensen discloses chromium polynicotinate, procedures for its synthesis and experimental use of the compound in laboratory experiments with rats. Brand-Miller discussed the glycemic index (GI) measurements of foods, diets with altered GI ratings and the effects of these diets on patients. The Examiner asserts that the claims of the present application are obvious in light of the disclosures of either McCarty reference in combination with the others.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. M.P.E.P. §2142. First, the prior art must suggest the desirability of the claimed invention. Second, the prior art must create a reasonable expectation of success in the practice of the invention under consideration. Third, all limitations of the claims of the present application must be taught or suggested. If the prior art fails to meet one or more of these criteria, a *prima facie* case of obviousness cannot be asserted.

Claims 1-20 are directed towards methods of treatment of dyslipidemia comprising the administration of a chromium complex and biotin. However, none of the prior art references, alone or in combination, suggest that biotin supplementation would influence in any way the level or composition of a patient's serum lipid profile. The McCarty references disclose methods that involve biotin supplementation and their effects on blood glucose levels. Even so, there is no discussion of any effects of biotin on serum lipid levels. The other references do not contain any mention of biotin. In all, the disclosures of the references do not suggest that there is any desirability or expectation of success in the use of biotin to influence serum lipid levels or treat dyslipidemia, alone or in conjunction with a form of chromium. With no mention of the effects of biotin on serum lipid levels, the prior art fails to teach the limitations of Claims 1-20 directed toward the use of a chromium complex and biotin for the treatment of dyslipidemia.

Claims 31-37 are directed toward the treatment of post-prandial hyperglycemia by the administration of a chromium complex and biotin. These methods are based on the surprising discovery of the effects of chromium and biotin supplementation on post-prandial hyperglycemia in particular, beyond the effects seen on fasting blood glucose levels or overall hyperglycemia with general dietary supplementation of chromium and biotin. In this case, the upward surge of glucose levels following a meal are reduced, thereby ameliorating the post-prandial hyperglycemic condition. However, the use of chromium and biotin to specifically target post-prandial hyperglycemia is not disclosed by any of the references. The McCarty references disclose methods for reducing general hyperglycemia in the long term with the administration of synthetic chromium tripicolinate and biotin, but do not disclose or suggest the specific treatment of post-prandial hyperglycemia. Thus, they focus on long term treatment of a chronic condition, not prevention of a transient one. Meanwhile, compositions or methods involving biotin supplementation are not disclosed by any of the other cited references. None of the references

suggest the desirability of or provide a reasonable expectation of success for a specific treatment of post-prandial hyperglycemia, i.e., a short term spike in blood glucose caused by eating food, with chromium and biotin supplementation.

The prophylactic effects of chromium and biotin supplementation on post-prandial hyperglycemia can be realized by adding chromium and biotin directly to foods themselves. The GI of a food is based on the peak and duration of elevated blood glucose levels after the consumption of the food. Hence, the inventors have discovered that the GI of a food can be directly lowered through the fortification of the food with a chromium complex and biotin. Accordingly, Claims 23-29 focus on methods of lowering the GI index of a food by administering a chromium complex and biotin to the food. Claim 30 covers foods treated in this way to have a lower GI. However, the administration of chromium and biotin to a foodstuff to lower that food's glycemic index are not disclosed or suggested by any of the references. Jensen describes experiments where rats are fed a synthetic laboratory-formulation diet that lacked any chromium. Some rats received chromium in the form of either chromium chloride or chromium nicotinate in their drinking water. Jensen found that the rats receiving chromium nicotinate in their drinking water had less intra-abdominal adipose tissue and a greater drop in serum lipid levels than the group receiving chromium chloride supplementation or control animals receiving no chromium. Even so, the effects of chromium supplementation on blood glucose levels were not examined and the reference is silent regarding hyperglycemia, glycemic indices and biotin. The McCarty references are silent with respect to glycemic indices and the treatment of post-prandial hyperglycemia. Meanwhile, compositions or methods involving biotin supplementation are not disclosed by any of the remaining cited references. Thus, the combined disclosure of the references does not suggest the desirability of or a reasonable chance of success for the treatment of post-prandial hyperglycemia with biotin and chromium supplementation or for the creation of lower GI foods with the administration of chromium and biotin. The claims of the present application are limited by the use of biotin in methods for the treatment of dyslipidemia and post-prandial hyperglycemia specifically and for the lowering of the GI of a food. These limitations are not taught in the prior art references.

The prior art references do not support a *prima facie* case for obviousness, as they do not provide any of the three required basic criteria. Applicants respectfully request the withdrawl of claim rejections based on 35 U.S.C. §103.

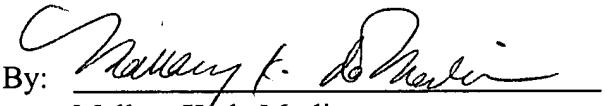
CONCLUSION

Based on the arguments above, Applicants request the removal of all claim rejections and assert the application is ready for allowance. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 8/18/03

By: 

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